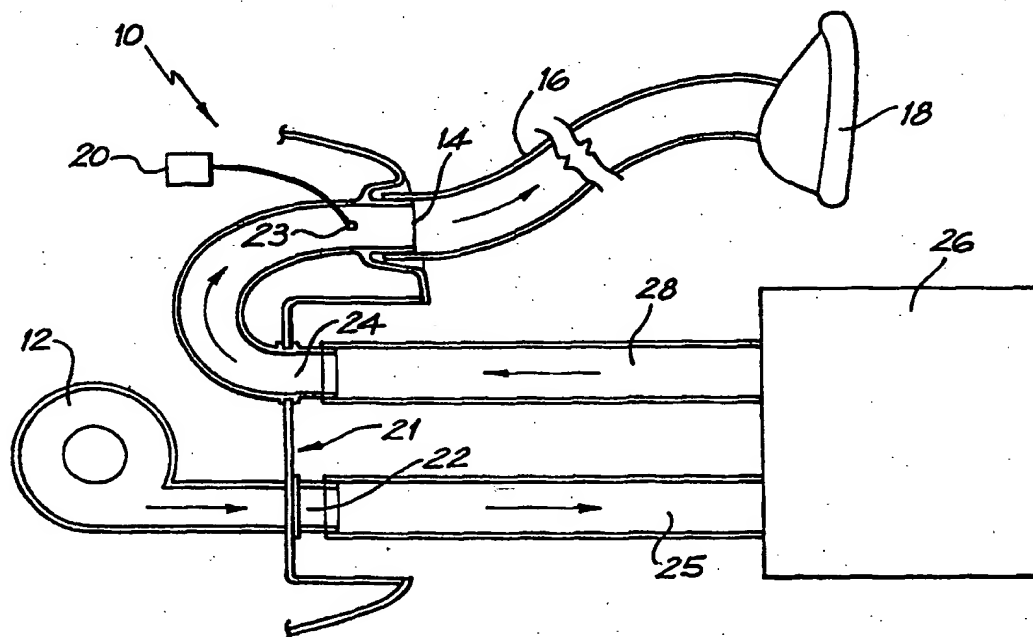




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61M 16/00</b>	<b>A1</b>	(11) International Publication Number: <b>WO 98/57691</b> (43) International Publication Date: 23 December 1998 (23.12.98)
<p>(21) International Application Number: PCT/AU98/00474</p> <p>(22) International Filing Date: 18 June 1998 (18.06.98)</p> <p>(30) Priority Data: PO 7422 18 June 1997 (18.06.97) AU</p> <p>(71) Applicant (for all designated States except US): RESMED LIMITED [AU/AU]; 82 Waterloo Road, North Ryde, NSW 2113 (AU).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): KENYON, Barton, John [AU/AU]; 20 John Street, Erskineville, NSW 2043 (AU). MARTIN, Dion, Charles, Chewe [AU/AU]; 1 Norman Street, Concord, NSW 2137 (AU).</p> <p>(74) Agent: SPRUSON &amp; FERGUSON; G.P.O. Box 3898, Sydney, NSW 2001 (AU).</p>	<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b> With international search report.</p>	

(54) Title: AN APPARATUS FOR SUPPLYING BREATHABLE GAS



## (57) Abstract

An apparatus (10) for supplying breathable gas. The apparatus (10) includes a flow generator (12), a gas outlet (14), a connection means (21) interposed between the flow generator (12) and the pressure sensing means (20), the connection means having a connecting inlet (22) and a connecting outlet (24), a pressure sensing means (20) interposed between the connecting outlet (24) and the gas outlet (14). The connection means (21) is adapted to allow selective connection to either a duct member (30) providing a direct flow path from the connecting inlet (22) to the connecting outlet (24) or to a humidifier (26) interposed between the connecting inlet (22) and the connecting outlet (24).

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## AN APPARATUS FOR SUPPLYING BREATHABLE GAS

### FIELD OF THE INVENTION

The present invention relates to an apparatus for supplying breathable gas.

The present invention has been developed primarily for use in Continuous  
5 Positive Airway Pressure (CPAP) treatment of, for example, Obstructive Sleep Apnea  
(OSA) in which pressurised air is supplied to a patient's airways to pneumatically splint  
them open. The pressure of the gas supplied to the patient can be constant, bi-level (in  
synchronism with patient breathing) or auto-setting in level. Throughout this  
specification any reference to CPAP is intended to incorporate a reference to any one  
10 of, or combinations of, these forms of pressurised gas supply.

The invention is also suitable for supplying gas for assisted respiration or  
mechanical ventilation.

### BACKGROUND OF THE INVENTION

Some people find breathing the cool, dry air produced by the flow generator of  
15 a gas supplying apparatus uncomfortable, leading to possible lack of treatment  
compliance. It can also cause a dry or runny nose. This problem can be ameliorated  
by placing a humidifier in the gas flow path between the flow generator and the patient  
to moisturise the gas supplied to the patient. A humidifier basically is a reservoir of  
water over the surface of which the pressurised breathable gas flows. The water can be  
20 heated (known as an "active" humidifier) or unheated (known as "passive").

In some gas supply apparatus, in particular those used in CPAP treatment, it is  
desirable or necessary to monitor the pressure of the gas being supplied at the mask  
worn on the patient's face. This is generally done by monitoring the pressure at the  
flow generator with an electronic pressure transducer and then compensating for the  
25 known flow characteristics of the delivery tube and mask by calibration to determine  
the mask treatment pressure.

However, if a humidifier is placed between the flow generator and the mask  
(downstream of the pressure transducer) its pneumatic impedance of the gas flow may  
result in large pressure swings and the introduction of errors into the mask pressure  
30 calculation. Moreover, if the pressure signal is used to measure snore as an indication  
of partial apnea, the humidifier may muffle the snore component thereby reducing the  
accuracy of the snore measurement.

It is known to ameliorate these problems by using a hollow cylindrical plug  
having a pressure sensing port connected by a flexible tube to a pressure transducer  
35 mounted within the housing that contains the flow generator. If the apparatus is used  
without a humidifier the plug has one end connected directly to the flow generator

outlet and the other connected to the mask supply tube inlet. When a humidifier is used, the humidifier inlet is connected to the flow generator outlet and the humidifier outlet is connected to one end of the plug. The other end of the plug remains connected to the mask supply tube inlet. In this way, the pressure monitored by the pressure transducer is downstream of the humidifier and not affected by its alteration of the gas supply path.

However, this apparatus suffers from several problems. Firstly, the usage of the plug and associated tube is messy and unsightly. Further, the tube is thin and prone to kinking and/or squashing leading to inaccuracies in pressure measurement. Also, if the tube is removed and inadvertently replaced with a tube of different length or diameter, the accuracy of the mask pressure calculation is adversely affected. Finally, the apparatus suffers from the possibility that the humidifier or plug may be incorrectly installed, particularly when used by patients in the home and/or with humidifiers manufactured by a third party.

The above disadvantages may be ameliorated by incorporating a humidifier into the housing that contains the flow generator. However, this is uneconomical as many patients do not require this feature.

Accordingly, there exists a need for an apparatus for supplying breathable gas which can be easily and simply connected to a humidifier and which may also be quickly and simply configured to function without a humidifier, in which gas supply pressure is sensed downstream of the humidifier, if present.

The present invention is directed towards achieving one or more of these needs and, in particular, to substantially overcoming or at least ameliorating one or more of the disadvantages of the existing apparatus described above.

## SUMMARY OF THE INVENTION

Accordingly, in the first aspect, the present invention discloses an apparatus for supplying breathable gas, the apparatus includes:

- a flow generator;
- a gas outlet;
- a connection means interposed between the flow generator and the gas outlet, the connection means having a connection inlet and a connection outlet; and
- a pressure sensing means interposed between the connection outlet and the gas outlet, wherein the connection means is adapted to allow selective connection to either a duct member providing a direct flow path from the connection inlet to the connection outlet or to a humidifier interposed between the connection inlet and the connection outlet.

The connection inlet receives gas from the flow generator. The connection outlet receives gas from the humidifier or the duct member, as the case may be.

Preferably, the breathable gas is air.

Desirably, the apparatus is connected by a gas supply tube to a patient "mask" to provide CPAP treatment, assisted respiration or mechanical ventilation. Mask varieties include nose masks, mouth masks, combination nose and mouth masks, nasal prongs, nasal pillows and full face masks.

The pressure sensing means is preferably an electronic pressure transducer.

The connection inlet and the connection outlet may be identical or may be different, for example in cross-sectional shape or diameter, in order to avoid incorrect installation of the duct member or the humidifier.

Preferably, the connection inlet and the connection outlet are recessed behind the outer edge of the casing or housing of the apparatus. In an embodiment, the duct member is in the form of a substantially U-shaped pipe adapted to connect the connection inlet and the connection outlet. The pipe preferably has an outer panel attached thereto which, upon installation, is substantially flush with adjacent outer panels of the casing or housing. In a preferred form the U-shaped pipe is comprised of two joined sections encased in a shape having a snap-engageable base and lid.

The humidifier can include a heater (ie. active) or be unheated (ie. passive).

In an embodiment, the apparatus also includes a gas flow rate sensing means interposed between the connection outlet and the gas outlet. In one form, the gas flow rate sensing means is a pressure differential flow sensor communicating with two pressure ports, the ports being respectively disposed on opposite sides of a flow impedance. In a preferred form, one of the pressure ports, preferably the port closest to the gas outlet, also communicates with the pressure sensing means.

The duct-member, and other components in the gas path, are desirably produced from antimicrobial materials. The duct member, and other components in the gas path, are also desirably disposable.

In a second aspect, the present invention discloses a CPAP treatment device incorporating the apparatus of the first aspect.

#### BRIEF DESCRIPTION OF THE DRAWINGS

A preferred embodiment of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Fig. 1 is a partial sectional schematic plan view of a first embodiment of a breathable gas supply apparatus according to the invention connected to a humidifier;

Fig. 2 is a view similar to Fig. 1, but showing the apparatus connected to a duct member;

Fig. 3 is a partial sectional schematic plan view of a second embodiment of a breathable gas supply apparatus according to the invention connected to a humidifier;

Fig. 4 is a view similar to Fig. 3, but showing the apparatus connected to a duct member;

Fig. 5 is a partial perspective view of the chassis of a third embodiment of a gas supply apparatus according to the invention connected to a duct member;

5 Fig. 6 is a view similar to Fig. 5 with the lid of the duct member removed;

Fig. 7 is a view similar to Fig. 5 with the duct member removed;

Fig. 8 is an exploded perspective view of the duct member shown in Fig. 5;

Fig. 9 is a schematic front view of another embodiment of the connection inlet and outlet; and

10 Fig. 10 is a schematic front view of a further embodiment of the connection inlet and outlet.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the Figs. 1 and 2, there is partially shown a first embodiment of an apparatus 10 for supplying breathable gas according to the invention. The apparatus  
15 10 includes a flow generator 12 and a breathable gas outlet 14. The breathable gas outlet 14 is connected by a flexible gas supply tube 16 to a face mask 18 worn by a patient (not shown). A connection means, indicated generally at 21, is disposed between the pressure transducer 20 and the flow generator 12 and includes a connection  
20 inlet 22 and a connection outlet 24. A pressure sensing means, in the form of a pressure transducer 20 connected to a port tapping 23, is disposed between the connection outlet 24 the gas outlet 14.

In Fig. 1, the connection inlet 22 is shown connected to the inlet tube 25 of a humidifier 26. The connection outlet 24 is connected to the outlet tube 28 of the humidifier 26. Thus, the pressure transducer 20 measures the gas supply pressure  
25 downstream of the humidifier 26 and is not affected any pneumatic impedance it introduces.

In Fig. 2, the apparatus 10 is shown configured without the humidifier 26. In this configuration, a duct member in the form of a substantially U-shaped pipe 30 provides a direct gas flow path from the connection inlet 22 to the connection outlet 24.

30 The main advantages of the apparatus are two-fold. Firstly, if a humidifier is used, gas supply pressure is measured downstream thereof and thus includes any pressure swings or variations introduced by the humidifier. Secondly, the apparatus can be quickly and easily converted between including, or not including, a humidifier in the gas supply path.

35 In the embodiment shown, the inlet 22 and outlet 24 are recessed behind the external boundary of the casing or housing 32 of the apparatus 10. The duct member 30 includes a panel 34 which, upon installation, is substantially flush with the casing 32 thereby providing a neat appearance to the apparatus 10.

Figs. 3 and 4 show a second embodiment of an apparatus 40 for supplying breathable gas according to the invention. Like reference numerals to those used in describing the first embodiment will be used to denote like feature with respect to the second embodiment.

5 The apparatus 40 includes a gas flow rate sensing means in the form of a pressure differential flow sensor 41 communicating with pressure tapplings 42 and 44 provided either side of a flow impeding orifice 46.

Flow impedance can also be accomplished by providing a straw bundle, flexible membrane, vortex former or the like between the tapplings 42 and 44.

10 Pressure measurement can be performed by using a separate pressure sensing means (not shown), such as the pressure transducer 20 and the tapping 23 from the first embodiment, or by measuring the pressure at one of the ports 42 or 44. The port 44 is preferable because it is closer to the gas supply conduit 16.

15 Figs. 5 to 8 show a third embodiment of an apparatus 60 for supplying breathable gas according to the invention. Like reference numerals to those used in describing the first embodiment will again be used to denote like features with respect to the third embodiment.

20 Figs. 5 to 7 show a mounting chassis 62 of the apparatus 60 with the upper external lid or cover removed. A pressure transducer (not shown) communicates with the supplied gas at port 64 provided in outlet tube 66. The tube 66 terminates in spigot 68 which is adapted for connecting to the gas supply conduit (not shown).

25 The chassis 62 includes a recess at 70 for fitment of a flow meter (not shown). A suitable flow meter is shown as item 50 in Figs. 6 to 10 of the applicant's international PCT patent application No. PCT/AU98/00082, the relevant disclosure of which is hereby incorporated by cross-reference. The flow meter shown in PCT/AU98/00082 includes a gas outlet in the form of a cylindrical tube (shown as item 58) which is positionable to protrude through U-shaped cut-out 72 (see Fig. 7) to constitute the connection inlet in a similar manner to the connection outlet 24 shown protruding from back wall 74 of chassis recess 76.

30 In this embodiment, the duct member 30 is comprised of two ABS plastic 90° tubes 77 connected by a DYNAFLEX (Trade Mark) thermoplastic elastomer connector produced by the GLS Corporation of OHIO, USA. Ends 78 and 80 of the duct member 30 include silicone 'O'-rings 81 coated with paralene. The duct member 30 is mounted within a box 82 comprising a base 84 and a lid 86 which are adapted to snap engage with one another.

35 The base 84 includes a recess 88 for engaging a tongue 88 (see Fig. 7) provided in chassis recess 70 to correctly position the box 82. The lid 86 includes a protuberance 90 which snap engages a complimentary recess in the lid (not shown) of

the apparatus 60 to retain the box 82 adjacent the chassis 62. The curved upper surface 92 of the box is a smooth continuation of the adjacent upper surface of the apparatus lid.

5 The U-shaped member 30 and the box 82 can be produced from an antimicrobial material or be disposable to reduce the risk of infection between different users of the apparatus 60. Other components in the gas path, such as the outlet tube 66, can also be made from antimicrobial material or be disposable.

Figs. 5 and 6 show the apparatus 60 configured for use without a humidifier. Fig. 7 shows the apparatus 60 in a configuration suitable for connection to the inlet and outlet tubes of a humidifier (after installation of the aforementioned flow sensor).  
10

Figs. 9 and 10 show two embodiments of the connection inlet 22 and the connection outlet 24. In Fig. 9, the inlet 22 and the outlet 24 are circular but of different diameter. In Fig. 10, the inlet 22 and the outlet 24 have different cross-sectional shapes. In both cases the ends of the duct member and the humidifier inlet and outlet are provided with corresponding engaging formations to avoid incorrect  
15 installation. This is especially advantageous when a non-symmetrical or uni-directional humidifier is used.

Although the invention has been described with reference to a specific examples, it will be appreciated by those skilled in the art, that the invention can be  
20 embodied in many other forms.



## CLAIMS:

1. An apparatus for supplying breathable gas, the apparatus includes;  
a flow generator;  
a gas outlet;  
5 a connection means interposed between the flow generator and the gas outlet,  
the connection means, the connection means having a connection inlet and a connection  
outlet; and  
a pressure sensing means interposed between the connection outlet and the gas  
outlet, wherein the connection means is adapted to allow selective connection to either a  
10 duct member providing a direct flow path from the connection inlet to the connection  
outlet or to a humidifier interposed between the connection inlet and the connection  
outlet.
2. An apparatus as claimed in claim 1, wherein the breathable gas is air.
3. An apparatus as claimed in claim 1 or 2, wherein the apparatus is  
15 connected by a gas supply tube to a patient mask to provide CPAP treatment, assisted  
respiration or mechanical ventilation.
4. An apparatus as claimed in claim 3, wherein the mask is a nose mask,  
mouth mask, combination nose and mouth mask, nasal prongs, nasal pillows or full  
face mask.
- 20 5. An apparatus as claimed in any one of the preceding claims including  
a gas flow rate sensing means interposed between the connection outlet and the gas  
outlet.
6. An apparatus as claimed in claim 5, wherein the gas flow rate sensing  
means is a pressure differential flow sensor communicating with two pressure ports, the  
25 ports being respectively disposed on opposite sides of a flow impedance.
7. An apparatus as claimed in claim 5 or 6, wherein one of the ports  
communicates with the pressure sensing means.
8. An apparatus as claimed in claim 7, wherein the port closest to the gas  
outlet communicates with the pressure sensing means.
- 30 9. An apparatus as claimed in any one of the preceding claims, wherein  
the pressure sensing means is an electronic pressure transducer.
10. An apparatus as claimed in any one of the preceding claims, wherein  
the connection inlet and the connection outlet are identical.
11. An apparatus as claimed in any one of claims 1 to 9, wherein the  
35 connection inlet and the connection outlet are different.
12. An apparatus as claimed in claim 11, wherein the connection inlet and  
the connection outlet are of a different cross-sectional shape or diameter.

13. An apparatus as claimed in any one of the preceding claims, wherein the connection inlet and the connection outlet are recessed behind the outer edge of the casing or housing of the apparatus.

14. An apparatus as claimed in any one of the preceding claims, wherein  
5 the duct member is in the form of a substantially U-shaped pipe adapted to connect the connecting inlet and the connecting outlet.

15. An apparatus as claimed in any one of the preceding claims, wherein the U-shaped pipe has an outer panel attached thereto which, upon installation, is substantially flush with adjacent outer panels of the casing or housing.

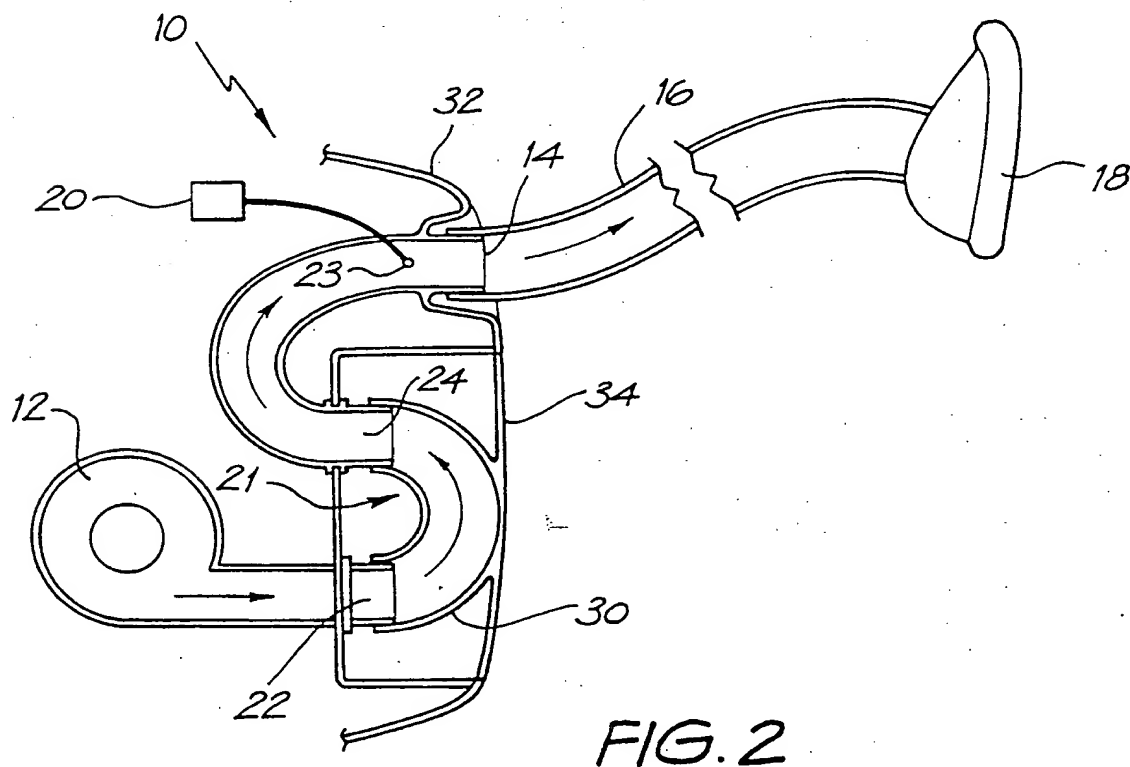
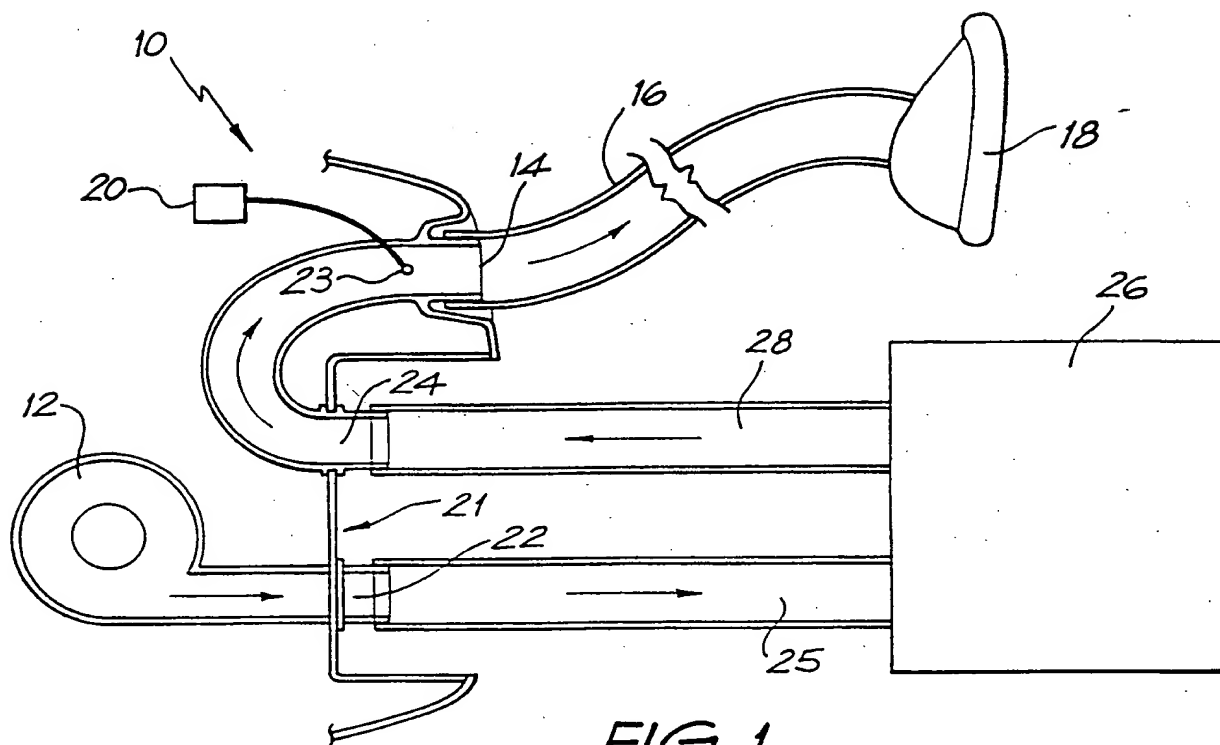
10 16. An apparatus as claimed in any one of claims 1 to 14, wherein the U-shaped pipe is formed from two joined sections encased in a box having a snap engageable base and lid.

17. An apparatus as claimed in claim 16, wherein the box is snap engageable with a housing or chassis of the apparatus.

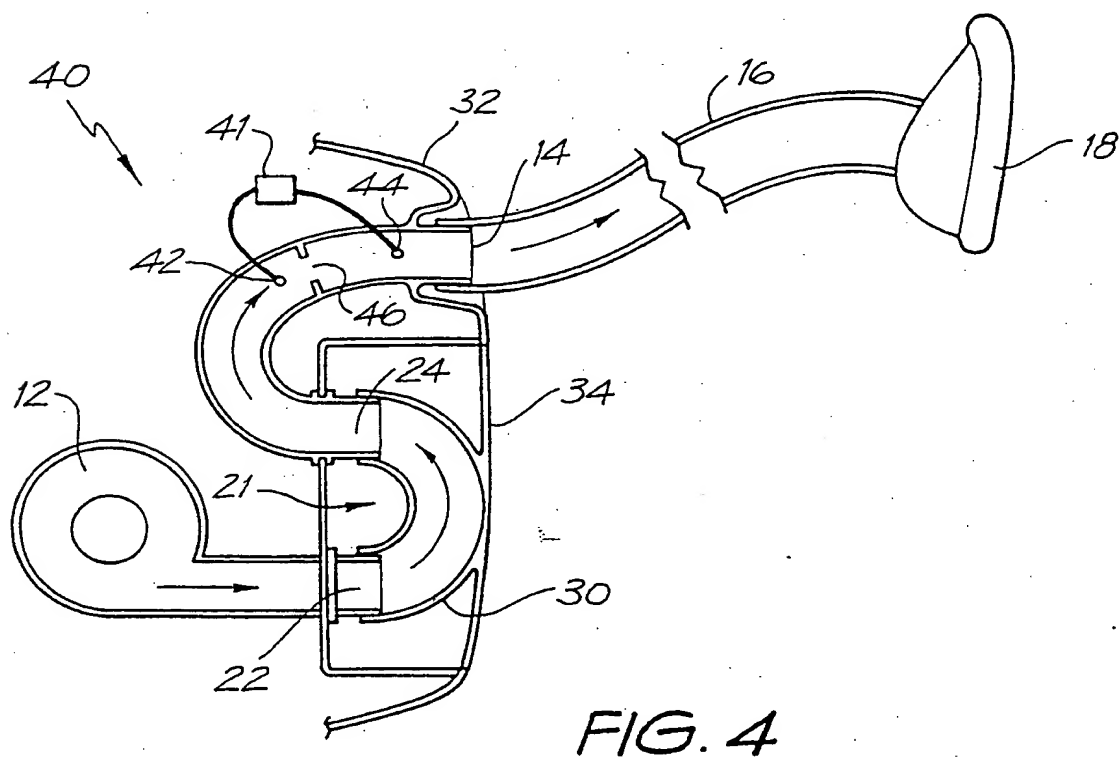
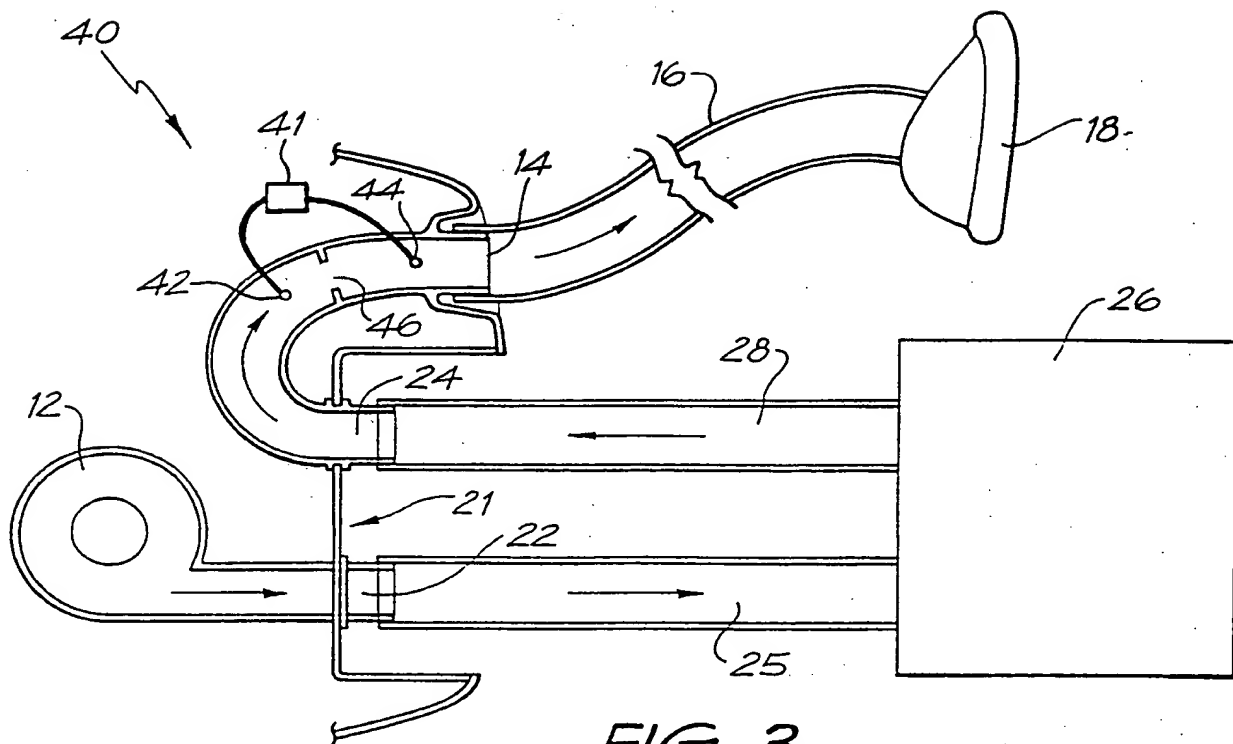
15 18. An apparatus as claimed in any one of the preceding claims, wherein the humidifier includes a heater.

19. An apparatus as claimed in any one of claims 1 to 17, wherein the humidifier is unheated.

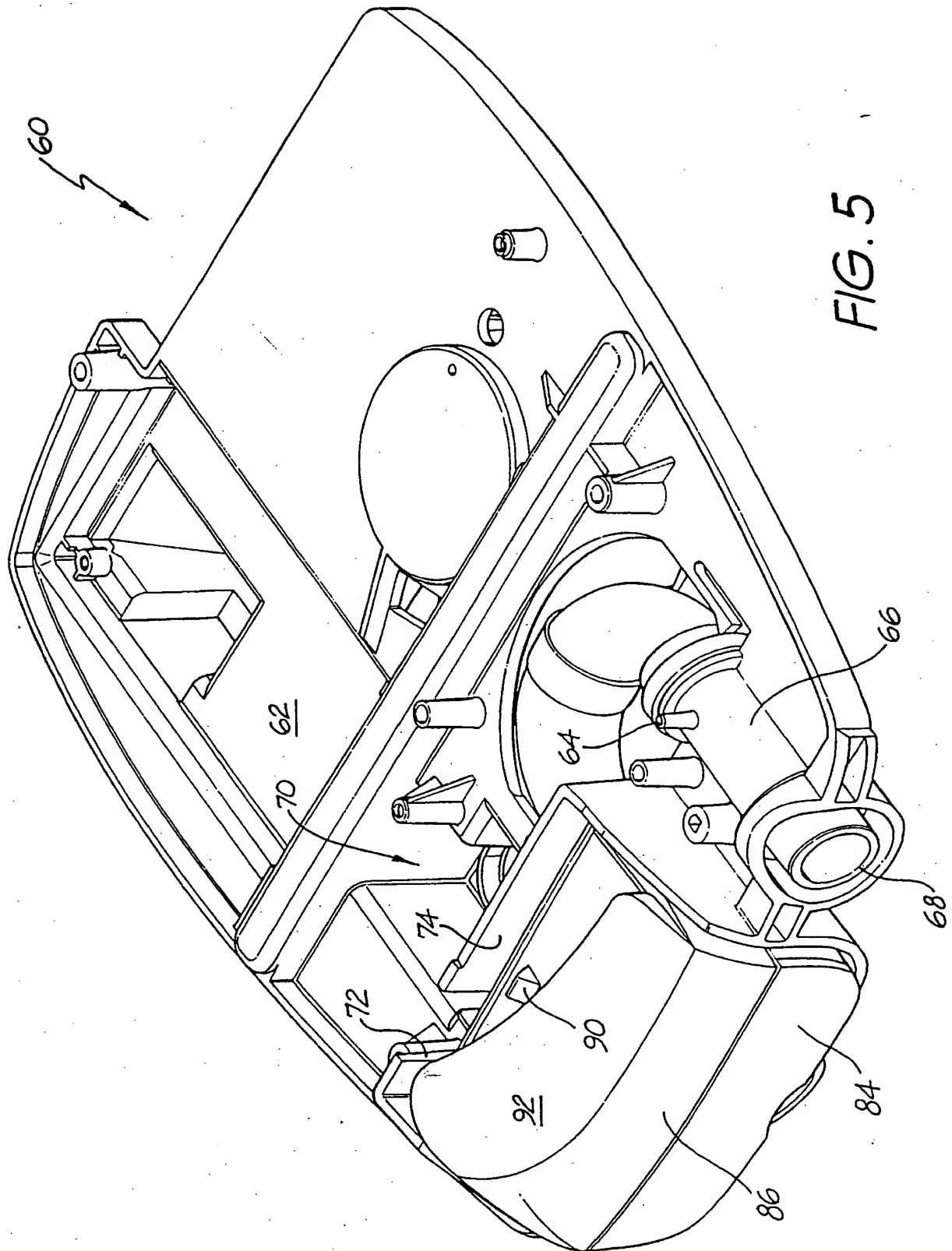
20 20. A CPAP treatment device incorporating the apparatus of any one of claims 1 to 19.



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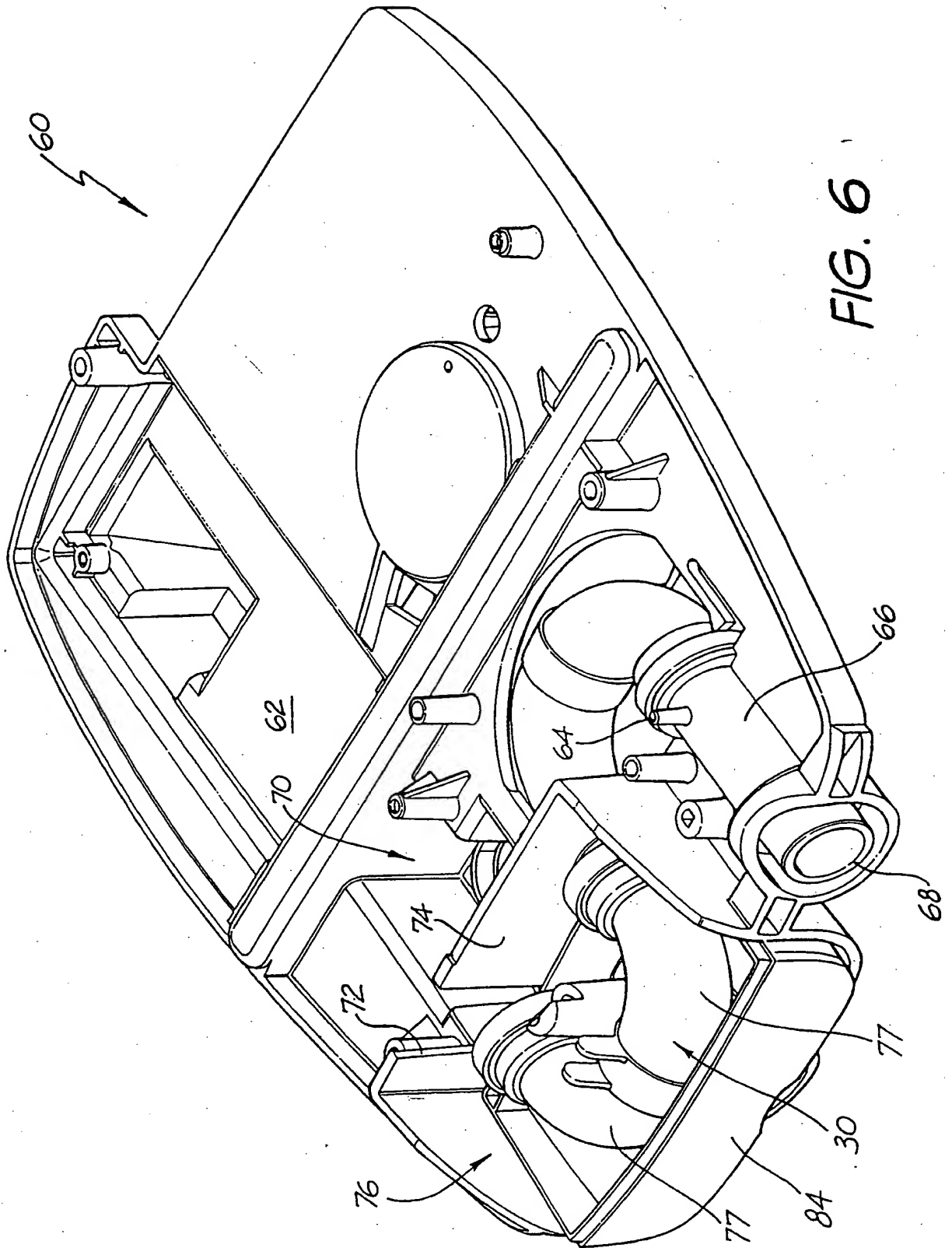
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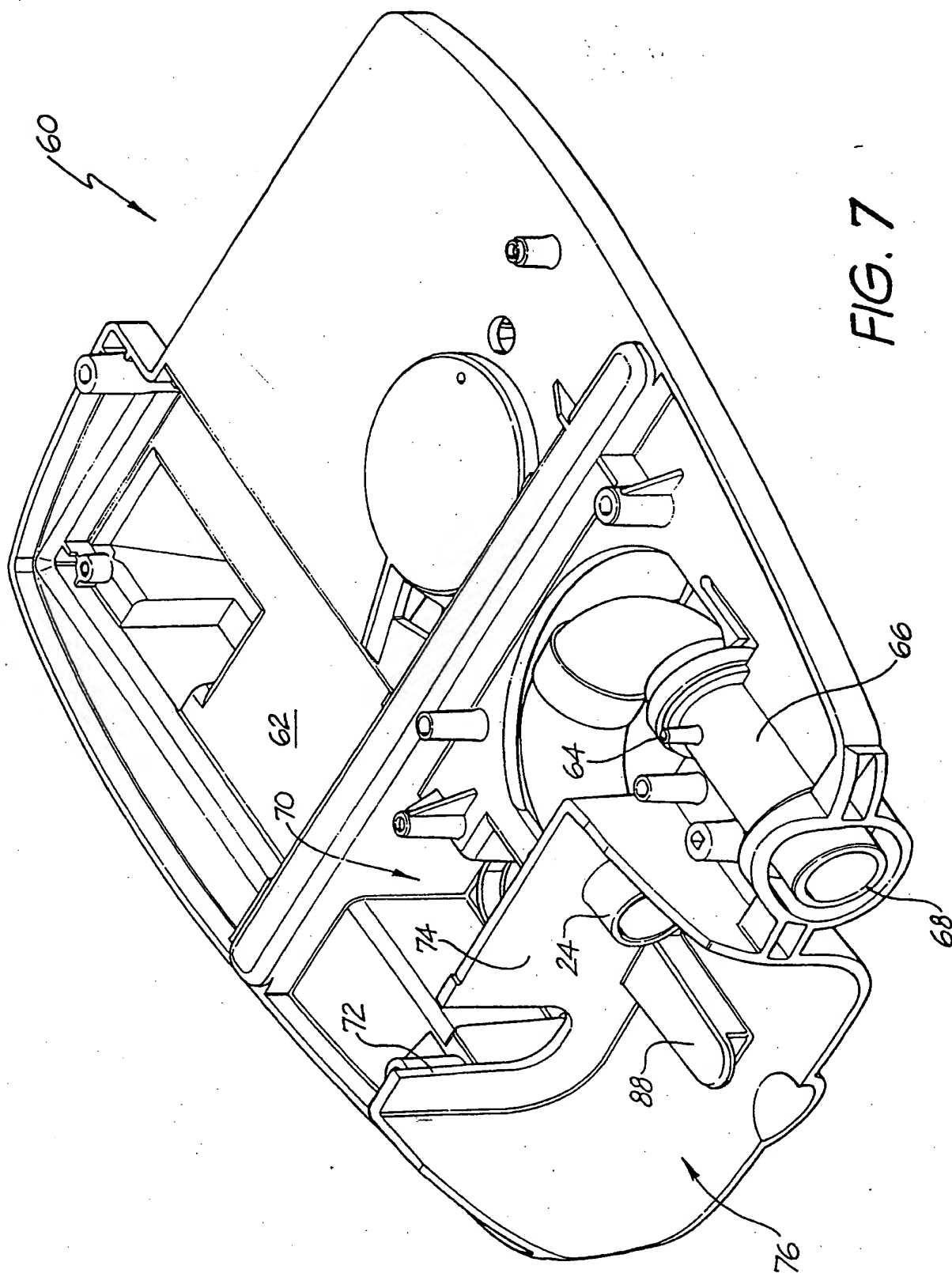


FIG. 7

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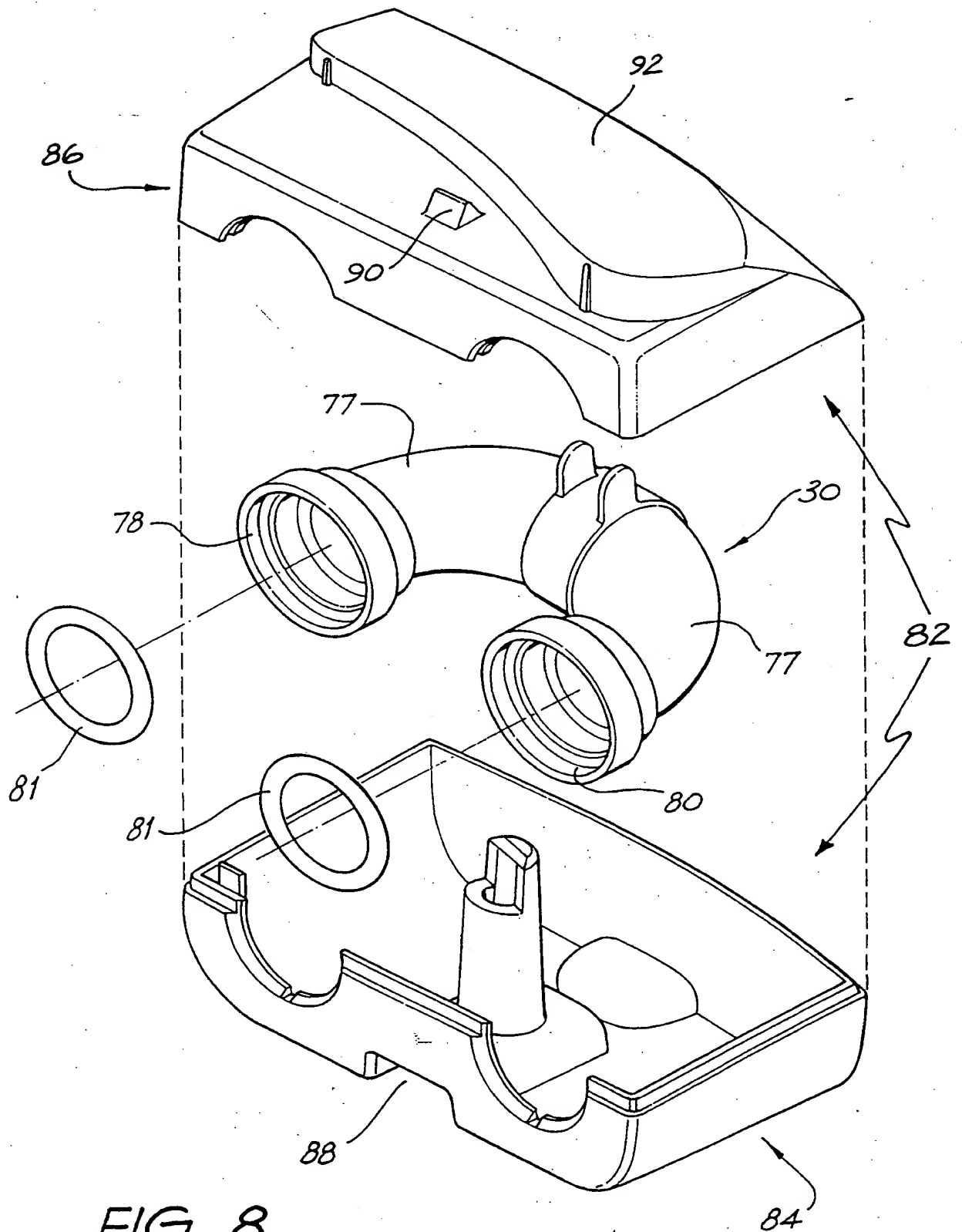


FIG. 8

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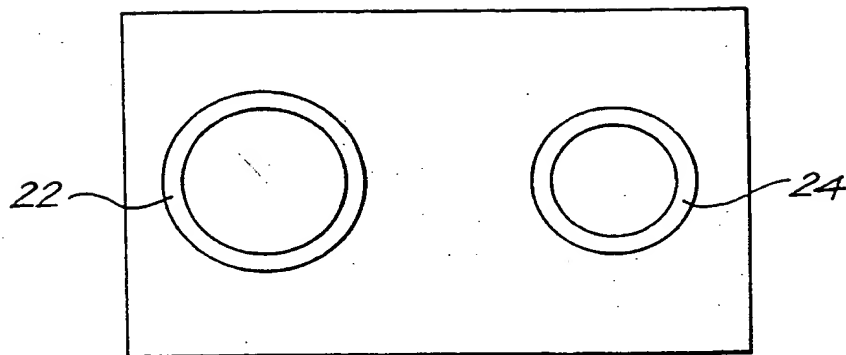


FIG. 9

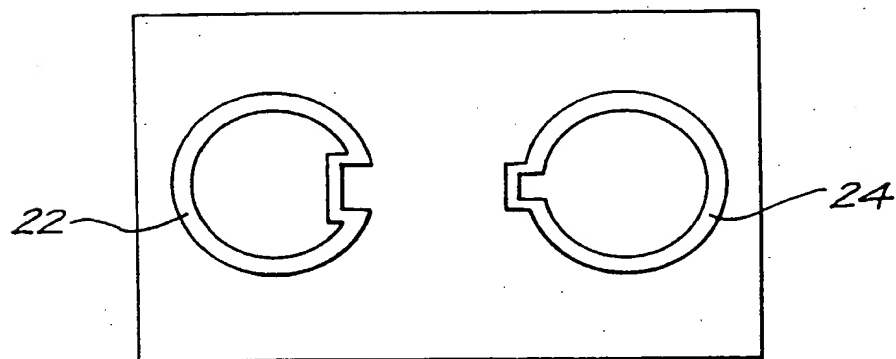


FIG. 10

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# INTERNATIONAL SEARCH REPORT

International Application No.  
PCT/AU 98/00474

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>																						
Int Cl <sup>6</sup> : A61M 16/00																						
According to International Patent Classification (IPC) or to both national classification and IPC																						
<b>B. FIELDS SEARCHED</b>																						
Minimum documentation searched (classification system followed by classification symbols) IPC: A61M 16/IC																						
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched																						
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) WPAT: HUMIDIFY, PRESSURE, SENSOR, TRANSDUCER, PROBE, RESPIRATION, BREATH VENTILATION, INSPIRATION, ANAESTHETIC, VAPOUR, CPAP, APNOEA, HYPOPNEA, SNORE, .CONTINUOUS, POSITIVE																						
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>																						
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.																				
X	US 5537997 A (MECHLENBURG et al.) 23 July 1996 Figure 5, column 13 lines 20-27	1-20																				
P, X	AU 42027/97 A (NETZER) 5 February 1998 Entire document	1-20																				
X	WO 82/03326 A1 (VAS-ÉS MUSZERIPARI SZÖVETKEZET) 14 October 1982 Figure 1, page 7 line 2 - page 8 line 34	1-5, 9-20																				
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex																						
<p>* Special categories of cited documents:</p> <table border="0"> <tr> <td>"A"</td> <td>document defining the general state of the art which is not considered to be of particular relevance</td> <td>"T"</td> <td>later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"E"</td> <td>earlier document but published on or after the international filing date</td> <td>"X"</td> <td>document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"L"</td> <td>document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"Y"</td> <td>document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"O"</td> <td>document referring to an oral disclosure, use, exhibition or other means</td> <td>"&amp;"</td> <td>document member of the same patent family</td> </tr> <tr> <td>"P"</td> <td>document published prior to the international filing date but later than the priority date claimed</td> <td></td> <td></td> </tr> </table>			"A"	document defining the general state of the art which is not considered to be of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	"E"	earlier document but published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	"O"	document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family	"P"	document published prior to the international filing date but later than the priority date claimed		
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"E"	earlier document but published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone																			
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"P"	document published prior to the international filing date but later than the priority date claimed																					
Date of the actual completion of the international search 31 July 1998		Date of mailing of the international search report 13 AUG 1998																				
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (02) 6285 3929		Authorized officer  STEVEN WEISS Telephone No.: (02) 6283 2466																				

## INTERNATIONAL SEARCH REPORT

International Application No.

PCT/AU 98/00474

## C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 298367 A2 (ADAHAN) 11 January 1989 Figure 4, column 2 line 20 - column 8 line 25	1-5, 9-20
X	EP 481459 A1 (DAR) 22 April 1992 Figure 1, column 2 line 58 - column 3 line 51	1-5, 9-20

## INTERNATIONAL SEARCH REPORT

### Information on patent family members

International Application No.  
PCT/AU 98/00474

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
US	5537997	US	5540219	US	5655522	AU	60474/96
		CA	2196918	EP	777507	WO	9640335
AU	42027/97	WO	9804311	DE	19630466		
WO	8203326	EP	74943	SU	1212315	US	4539984
EP	298367	JP	1034374	US	4823787	US	4807616
		US	4941469	CA	1298167		
EP	481459	IT	1243853				
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